



George

RESEARCH

NEWSLETTER OF THE GEORGE INSTITUTE FOR INTERNATIONAL HEALTH

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The changing face of R&D

Joining forces to make a difference

Expanding the scope of its policy and practice program, The George Institute recently added a new team to its project portfolio. The Pharmaceutical Research and Development Policy Project (PRPP) is an independent policy unit that was established in May 2004 at the London School of Economics and recently transferred to The George Institute. The PRPP aims to develop new pharmaceutical research and development (R&D) policy tools to be implemented by Western governments and donors.

Sponsored initially by the Wellcome Trust and subsequently by the Global Forum for Health Research through contributions from the World Bank, the PRPP comprises a small high-level staff with experience in regional health issues, neglected diseases, health economics, pharmaceutical industry R&D, intellectual property, and public policy formulation.

Government incentives and policies to stimulate pharmaceutical research and development (R&D) for "non-commercial" diseases, such as malaria, TB, sleeping sickness and some "Western" diseases, are failing to deliver the necessary public health outcomes. This is largely due to a lack of empirical information on the costs and effectiveness of various R&D approaches which, in turn, leads to poorly formulated public R&D investment strategies and policies.

The PRPP aims to address these deficits by:

- providing policy-makers with information and analysis of the performance of existing R&D for non-commercial diseases;
- developing recommendations and policy tools, which are aimed at improving the productivity of public and philanthropic R&D funding for non-commercial diseases.

The George Institute offers an excellent skill base for the PRPP, both because of its focus on public health issues in low and middle-income developing countries, and its extensive experience in pharmaceutical clinical trials in these regions. This commonality of interest and experience will be invaluable in supporting the PRPP's current work on funding mechanisms for clinical trials of new malaria products.

The landscape of neglected disease

Director of the PRPP, Dr Mary Moran, says "The landscape of neglected-disease drug development has changed dramatically over the past five years."

Leading the Pharmaceutical R&D Project at the London School of Economics and Political Science, Dr Moran and her team assessed the state of drug development for neglected diseases. Their focus was on the developing world, and included diseases such as malaria and tuberculosis, which kill around three million people each year.

"Traditionally it was widely understood and accepted that diseases of poor nations have not been of any interest for large pharmaceutical companies, compared to drugs for the 'rich world' for diseases such as diabetes and depression," said Dr Moran.

Contrary to this popular belief, their investigations showed (in the report *The new landscape of neglected disease drug development*) that, since 2000, there has been a shift in activity. "We found that there were over 60 new drug projects targeted at neglected diseases. Interestingly, around 75% of all projects were from public-private partnerships (PPPs). These partnerships coordinate large pharmaceutical companies with academics, non-government and multi-lateral groups like the WHO. They raise money to fund drug development, co-ordinate the R&D process and manage the overall portfolio to make sure the most promising projects get top priority."

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A Message from the Principal Directors



Australia's role in international health

Thank you for your encouraging feedback regarding the inaugural issue of *George Research*. We trust our newsletter will continue to update you with the latest news from the Institute and we have taken the opportunity in this, the second issue, to highlight our latest work and developments in Indigenous health outcomes, brain injury in rugby players, and the Pharmaceutical Research and Development Policy Project (PRPP), in addition to a review of our thoughts on the current climate of global health.

Recently we celebrated World Health Day, where, at The George Institute, we called for more concerted action to be directed towards the prevention and treatment of chronic diseases in poorer regions of the world.

Whilst the control of infectious diseases in Asia, such as bird flu, has been deemed to be a high health priority, diseases such as this remain of relatively minor importance when compared with chronic diseases.

Chronic diseases pose a serious threat to development and the alleviation of poverty, yet they remain largely neglected by governments and aid agencies worldwide. If the United Nations' Millennium Development Goals are to be achieved by most countries in the Asia Pacific region, the prevention and control of these diseases must be made a priority.

In developing countries, the victims of chronic disease are frequently middle-aged people in the prime of their working lives – depriving families of income earners, workplaces of employees, and communities of leaders. Additionally, it is the poor in these countries who will suffer most as a consequence of both higher disease risks and limited access to health care. In several parts of Asia, more than 10% of the population has diabetes, whose outcomes in these regions include amputation, heart disease and death.

A focus on chronic disease in low to middle income countries is long overdue and we urge the Australian government, AusAID and other agencies, to reconsider their priorities and include the control of conditions such as diabetes, heart disease and stroke in their aid programs.

The George Institute, as part of its international health focus, operates research programs addressing chronic disease in China and India. These countries have two of the world's largest populations, and both were included in the study that led to the WHO report *Preventing Chronic Diseases – A vital investment in late 2005*.

The causes of chronic disease in low-income countries are largely the same as those in western countries and include smoking, obesity and other dietary factors. The WHO report noted that even a 2% reduction in mortality due to chronic disease could save over 35 million lives in the next 10 years.

Treatment and prevention strategies that have been shown to work in high-income countries can also be applied to developing countries if the systems are in place to deliver appropriate care. Australia, for example, has been a global leader in controlling chronic diseases and its experience as well as resources would allow it to make a major contribution to the control of these same diseases among its regional neighbours.

We are thankful for the support of our global collaborators, so that the Institute can work towards mitigating the effects of chronic disease and injury, particularly in countries without adequate education, research and health resources.

However, we hope that the Australian government and relevant agencies see the massive influence they can have on the incidence and impact of chronic disease and take greater action to relieve this growing epidemic as a matter of urgency.

Robyn Norton

Stephen MacMahon

The George Institute for International Health

The changing face of R&D

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In recent times PPPs were non-existent. This year, Dr Moran says, four PPPs are now focused on producing these drugs and nine products should become available on the market in the next five years. Only 13 new drugs for neglected diseases were developed by pharmaceutical companies prior to the advent of PPPs, with only one of these drugs being suitable for developing country use.

"Key players are now working smarter, by forming a mutually beneficial partnership that eliminates a lot the financial risk that was involved in the past. This results in a joining of finances, time, expertise and resources, which will benefit poor countries who cannot afford developed-world drug prices." Dr Moran added.

The 1993 report *Investing in Health* released by the World Bank, notes that an estimated US\$41 spent per person on diseases in poor countries would reduce the burden of disease and would improve economies. Interestingly enough, this is 1/30th of what was spent per person in high-income countries at this time.

Surprisingly, Dr Moran said that multinational drug companies are now more interested in managing the public relations risk that stemmed from neglecting poor country patients rather than

purely making financial returns on drugs. For these companies, neglected disease R&D presented a cost-effective way of keeping governments and critics happy and taking the heat off debates that threatened to weaken drug companies' patent rights. Smaller companies and academics were also increasingly active in the area, motivated by the presence of PPP funding and the promise of PPP assistance in moving their projects from the bench top to the patient.

While the shift in R&D in this area is a step in the right direction, government funding accounts for less than 20%. The PRPP has held discussions with governments and donors following their popular report. The project team has briefed stakeholders on their significant findings with the aim to influence their policies.

Recently Dr Moran and her team talked to the UK, Irish and Netherlands governments and subsequent announcements show their actions to be effective, as the UK has since pledged £22.5 million and the Irish recently announced nine million to MMV, and 360,000 to the TB Alliance.

The next step

The new project funded by the World Bank aims at determining the funding required to support

clinical trials of current and future malaria drug and vaccine portfolios.

This study will assess both direct and indirect project costs, such as those related to trialing the new products and to improving trial infrastructure. Based on this information, the PRPP hope to provide donors with a clearer picture of where funding gaps or duplications exist, and possible new approaches to streamline and coordinate donor inputs to the malaria clinical trial process.

The main objectives of the new project are:

- To quantify the funding needed to conduct clinical trials of new anti-malarial products (drugs and vaccines), including trial capacity building and project costs for Phase I-IV trials;
- To identify efficiencies to reduce malaria product trial costs;
- To determine how resources for these trials should best be allocated;
- To develop a coordinated mechanism(s) to deliver these resources;
- To assist with implementation of the chosen mechanism(s), as requested.

Staff Profile



GEMMA STARZEC
Clinical Data Manager
BSc. (Hons) Applied Biological Sciences

Gemma joined the data management team at The George Institute in June 2005, where she manages the design, testing and maintenance of databases and websites of the various projects of the Institute.

In her role as Clinical Data Manager, Gemma runs validation checks on data received throughout the

course of a study. Currently Gemma is working on the INTERACT and QUEST studies, which are assessing aspects of stroke management and prevention around the world and in China respectively.

Gemma always held an interest in cancer research, but didn't feel laboratory work was for her. "An opportunity came up at Novartis in the UK, working on a Phase II leukemia drug."

Gemma found working on the study extremely rewarding. "The results were enormous, we received emails from people who were once bed-ridden and now running marathons" says Gemma.

Gemma's career then traveled 'down-under' to AstraZeneca in Sydney, where she worked mainly on stroke and gastroenterology studies.

Her decision to join The George Institute she describes as "A breath of fresh air! Having always worked for pharmaceutical companies The Institute gave me the

opportunity to work on health projects as well as drug studies."

Gemma is also a self-confessed 'Hoopaholic'. "I got seriously hooked about six months ago. At first it was a challenge keeping it up but as soon as I learnt my first trick there was no stopping me," says Gemma.

While most people can't remember when they last picked up a hula-hoop, Gemma can't put them down. "My signature moves are foot hooping and 'The Mummy' where you jump into the hoop and wrap it round your body into a lasso. I still feel like a beginner, but I can hoop both clockwise and anti-clockwise and do most tricks. It's a great way for me to unwind and switch off from the world."

Gemma hopes to perform one day and has recently joined a 'hoop troop'. Keep your eye out for this 'Hoopaholic' at festivals in the future.

ROAD TRAFFIC INJURY: A BIG PROBLEM FOR GLOBAL HEALTH AND FOR AUSTRALIANS TRAVELLING IN ASIA



A major review published in *The Lancet* has revealed the enormity of road traffic injuries in countries that can least afford to meet the health and economic costs. As the numbers of road injuries and deaths continue to rise, the escalating risk for the increasing numbers of travelling Australians is of great concern.

The authors of the review, from The George Institute, the University of Auckland, New Zealand and the National Institute of Public Health in Mexico, believe that while motorisation has enhanced the lives of many individuals and societies, the benefits have come with a high price, highlighting a critical need to address road traffic injuries as a public health priority.

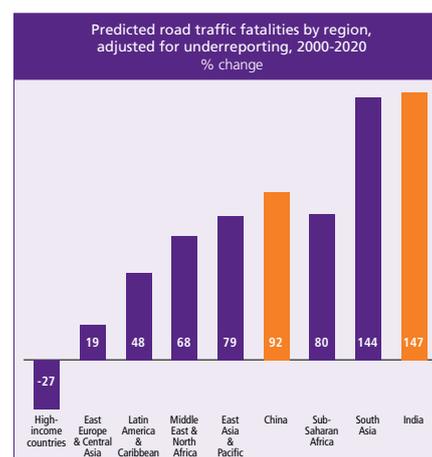
Professor Robyn Norton, Co-Principal Director of The George Institute, says that “Although the number of lives lost in road crashes in high-income countries has decreased in recent decades, for the majority of the world’s population the burden of road traffic injury is increasing dramatically in terms of societal and economic costs.”

In 2002, 1.2 million people were killed and 50 million injured in road traffic crashes worldwide, costing an estimated US\$518 billion. In low and middle income countries, the economic costs of road crashes are estimated to exceed the total amount of

development assistance these countries receive annually. “Without appropriate action, road traffic injuries are predicted to escalate from being the ninth leading contributor to the global burden of disease in 1990 to the third leading contributor by 2020,” Professor Norton added.

“The World Bank reports that in 20 years the global road death toll will increase by 66%, although this figure hides a significant divergence between rich and poor nations. While a 28% reduction in fatalities is expected in high-income countries, increases in fatalities of 92% and 147% are anticipated in China and India, respectively.” As Australian involvement in both China and India continues to grow, the numbers of Australians at risk is also likely to grow.

The Lancet paper identifies the vulnerability of some road user groups, particularly pedestrians and two-wheeler users, who are vastly over-represented among crash victims at a global level. Studies in Asia show that motorcyclists have particularly high rates of injury whereas in Africa pedestrians are the most frequently injured road users. However with the rates of motorization increasing dramatically in countries such as India and China, the proportion of motor vehicle occupants at risk of injury is likely to increase.



“Recognition of road crashes as a major public health problem that is predictable and preventable is essential in addressing this emerging epidemic,” said Professor Norton. “Many high income countries, such as Australia, have had dramatic successes in reducing the incidence of road traffic injuries in recent decades despite increases in motorization. Australian expertise can thus play an important role in helping countries in the region to modify and implement intervention strategies that are known to be effective.”

“Many strategies to produce safer people, safer roads and safer vehicles had shown success in reducing fatalities and casualties”,



Professor Norton said. For example, introducing graduated driver licensing systems reduced road crash injury rates among 16-year-olds by 28% in wealthier regions; the introduction of speed humps in Ghana showed a 55% reduction in all road traffic deaths; use of daytime running lights for motorised two-wheelers led to a 15 % reduction in fatal daytime crashes in Singapore; and use of seatbelts has been shown to reduce the risk of serious injury by 40% and fatal injury by 65%, although vehicles in many low and middle income countries often lack functioning seatbelts.

The authors of *The Lancet* review also emphasise the importance of establishing surveillance systems that will monitor patterns of injuries and impacts of preventive strategies. Such surveillance systems must capture not only deaths but also non-fatal outcomes, given the potentially catastrophic impacts of non-fatal injuries on families and communities who must care for these individuals.

“A continuing global commitment to address the growing problem of road traffic injuries is required,” said Professor Norton. “This must recognise the disparities in the experience of road injury based on income and social context, between and within countries.”

\$2.8million announced for health research study for Indigenous Australians

The National Health and Medical Research Council has announced a \$2.8 million research grant for a study aimed at improving the health outcomes of Aboriginal Australians with chronic disease.

The research, to be conducted by The George Institute for International Health, the Menzies School of Health Research and six Aboriginal Medical Service sites, will use the substantial funding over five years to identify existing health system barriers and develop strategies to reduce obstacles to essential care.

The federal government’s investment highlights the urgent need to address the difficulties faced by Indigenous Australians in accessing health services, as well as the high rates of heart and kidney disease in Aboriginal people.

Dr Alan Cass, Director of the Renal Division at The George Institute, says the research will explore the reasons for poor access to necessary care for chronic diseases.

“We will develop and trial new strategies in partnership with Aboriginal people aiming to improve real health outcomes. The research is focused on understanding barriers to necessary care, and addressing them to improve health. We will also draw heavily on patient, community and health provider perspectives,” says Dr Cass.

“The research will unite senior doctors, Indigenous community, health researchers, policy makers, health workers, patients and communities across three states – New South Wales, Queensland and the Northern Territory,” he added.

Dr Noel Hayman, Clinical Director of Inala Indigenous Health Service and a Chief Investigator for the study, stresses the need



Aboriginal artwork by Wenten Rubuntja installed in the Araluen Art Centre in Alice Springs

to provide the best possible service to everyone.

“The involvement of all key players in this research will ensure positive outcomes for patients that we care for. Successful prevention and treatment strategies for chronic disease are available throughout the country. In this study we will review why Aboriginal Australians are not accessing the benefits of improvements in health systems experienced by other Australians in terms of heart and kidney disease,” said Dr Hayman.

This study is part of the Renal Division at The George Institute that focuses on the development and implementation of treatment and prevention strategies for kidney disease. This study exemplifies the efforts of the division to improve equity in health outcomes and equity in access to health care for patients with kidney disease.

THE MILD-TRAUMATIC BRAIN INJURY (MTBI) STUDY

Brain injury study in rugby players to enhance safety and recovery



Photo courtesy of Sportography

A study into improving the management of players involved in contact sports following a concussion is currently underway at The George Institute.

The study is investigating mild-Traumatic Brain Injury (mTBI) among non-elite rugby union and league players in metropolitan Sydney and will provide evidence upon which guidelines/policies can be developed that manage a player's return to the sporting field following a concussion.

More than 2200 rugby players from various schools and clubs around Sydney have been recruited to the study. Last year more than 1200 players were observed throughout the rugby season. Thanks to the support of schools and clubs, research staff are able to examine the rate of mTBI and assess the risk and protective factors for injury and recovery.

Professor Mark Stevenson, Senior Director, Research and Development at The George Institute said there is an immediate need for a study of this kind, stating that "the guidelines that currently exist for players who sustain a concussion or mild traumatic brain injury are inconsistent."

"The lack of evidence-based guidelines has led to ad hoc decisions, which can endanger the player's recovery and safety. To develop effective guidelines information is needed not only on how often head injuries occur, but what the risk and protective factors for these injuries are and importantly, how players recover following a concussion," he added.

Upon completion of the project, 3,500 rugby union players aged 16 to 35 years will have been assessed. To date, there are inconsistent guidelines on the management of mTBI in returning a player to the field. This study will provide the evidence needed to create new guidelines.

The George Institute is undertaking the study in collaboration with the School of Safety Science and the NSW Injury Risk Management Research Centre, University of New South Wales, and the University of Pittsburgh Medical Center, Center for Sports Medicine, USA. The Institute acknowledges the Centers for Disease Control and Prevention, USA for funding the research.

For further information on this study go to www.thegeorgeinstitute.org.

Concussion in sports seminar

On March 24, The George Institute hosted an evening on the issues surrounding mTBI in rugby headlined by guest speaker Dr Mark Lovell, an international consultant in neuropsychological testing. Dr Lovell emphasised the importance of understanding the impact of mTBI and showed that it is of growing interest in the US.

The evening was attended by physiotherapists and managers of community rugby around the Sydney area. As well as a fascinating segment by Dr Lovell who drew on his experience with the American NHL and NFL, Professor Mark Stevenson, Dr Andrew McIntosh and Associate Professor Arthur Shores also presented on various aspects of mild traumatic brain injury in sport. You can read more about the events of the Institute on page eight of this newsletter.

Staff profile



COLMAN TAYLOR
Research Officer
BPhed, MNutDiet

Colman's career interests have always been in the area of health, and more recently in the area of sports and road traffic injury.

Commencing work at The George Institute early 2006, Colman is the Research Officer in the Critical and Trauma Care Division at the Institute on the Mild Traumatic Brain Injury (mTBI) in Rugby Players as well as the Heavy Vehicle study.

"Working towards providing increased safety to rugby players I find extremely rewarding," says Colman. "The mTBI study is looking at the incidence of sport-related concussion and assessing the risks and protective factors for injury and recovery. Importantly, the study will develop guidelines for return-to-play decisions for players following mTBI. Currently I am also planning a large-scale heavy vehicle study, investigating crash risk, with the injury prevention and musculoskeletal team, which is awaiting funding confirmation."

Colman says what makes working at The George Institute so great is "The opportunity to work in public health and the provision of career development opportunities. This, coupled with the ability to work with experts in the field and being able to work in a stimulating and challenging environment, is a real draw-card." However, the coffee machine and the view from my desk really top it off" In the short term, he is focused on achieving a PhD, "My longer-term focus is open to the new opportunities that are constantly arising at the Institute"

"I have always been interested in the many diverse areas of public health. Working in research satisfies this wish, as it gives me the opportunity to work at the front line in a constantly evolving environment."

Not surprisingly, Colman's interest in rugby is personal. When he's not socialising, collecting bottle caps or surfing, "During the winter months I play rugby and there is the possibility I will make a mid-season appearance for Hunters Hill." We will watch with interest to see if Colman ends up participating in his own study!

Study reveals Maori and Pacific Islanders have increasing incidence of stroke

A study by The George Institute published in *Stroke*, investigating trends in stroke incidence in Auckland, New Zealand shows Maori and Pacific peoples are suffering more strokes than other ethnic groups. The data from two decades of research reveals that stroke attack and incidence rates have increased in Pacific peoples since 1981, to almost double that in New Zealanders of European origin (NZ/Europeans).

Stroke is a major health problem that affects around 17 million people globally. Auckland's population is one of the most ethnically diverse in New Zealand and, until now, limited data has been available on ethnic differences in stroke risk and outcome. The study, led by Prof Craig Anderson and Kristie Carter, Pacific Health PhD scholar, from the Health Research Council of New Zealand, in collaboration with the University of Auckland, assessed data accumulated over a 20 year period, from general practitioners, hospital records, questionnaires and interviews.

"Encouraging declines in the rate of stroke among NZ/Europeans in Auckland have taken place over the last 20 years, yet, in the same period, Maori and Pacific populations have shown a near doubling of stroke incidence," says Carter.

In Maori and Pacific people, in particular, strokes are now occurring more frequently and at a younger age - on average up to 10 and 15 years earlier than in NZ/Europeans.

"These divergent trends and ongoing ethnic disparities in stroke call for urgent development and the implementation of prevention strategies for different ethnic groups in New Zealand." Ms Carter said.

"Significant changes in the patterns of stroke management were identified over the 20 year period, however substantial action to improve prevention strategies must be planned as the



local and global burden of stroke intensifies due to ageing of the population".

Ms Carter also points out that the positive changes in the profile of health risk factors, such as declines in smoking, were offset by increasing, or ongoing, high frequencies of diabetes and obesity in all ethnic groups.

In addition, data showed NZ/Europeans experienced less severe strokes than other local ethnic groups, which may reflect differences in accessing diagnostic investigations or management of the illness for the different groups. The findings of this study mirror similar results in African-Americans compared with Caucasians in the United States and related studies in the United Kingdom. "While genetic factors may be one explanation for these disparities, differences in socioeconomic circumstances, exposure to risk factors and access to services that assist in managing risk factors may also be significant, said Ms Carter"

The study was funded by the Health Research Council of New Zealand and was facilitated by The George Institute in collaboration with the University of Auckland, as part of the Auckland Regional Community Stroke (ARCOS) Study Group.

Update on The George Institute Events

The George Institute regularly hosts events on the latest research breakthroughs and developments. Events such as evening seminars through to two-day courses are frequently on offer through the Institute, both on and off-site.

Representing the broad nature of the Institute, events focus on policy and practical implications of injury (driver distraction, mobile phone use), musculoskeletal conditions, epidemiology, public health, cardiovascular and renal disease to name a few. Local and international guest speakers often headline seminars and courses on offer drawing on a range of opinions and experiences.

In line with the Institute's goal to diminish the effects of chronic disease and injury, mostly in countries without adequate education, research and health resources, events are often based, or maintain a strong focus, on India and China.

To ensure that you are kept up-to-date with our latest events, contact Events Coordinator, Evangelie Barton ebarton@thegeorgeinstitute.org or visit www.thegeorgeinstitute.org.

39TH INTERNATIONAL TEACHING SEMINAR TO BE HOSTED BY THE GEORGE INSTITUTE

Since 1968, the World Heart Federation has convened an immensely productive and rewarding meeting in cardiovascular disease. The annual seminar aims to educate delegates in epidemiologic studies and to strengthen the efforts to prevent mass cardiovascular disease.

To date, over 1000 physicians and scientists from over 100 nations have attended the seminar, and 38 meetings have since taken place in 33 different countries such as Finland, Yugoslavia, Norway, Brazil and Tunisia. This October, Australia will host the seminar for the first time, as The George Institute, was given the honor of convening the 39th meeting.

Founders of the ten-day teaching seminar on cardiovascular disease epidemiology and prevention recognized the need for training in research, and also the constraints on time and resources limiting the ability of workers in less developed countries to obtain training. The Institute will sponsor 38 fellows on the ten-day course. The candidates will gain a basic understanding of the epidemiologic and statistical tools needed to undertake and evaluate research, a general perspective of cardiovascular disease epidemiology, the evidence base for preventive practice, and translation of research evidence into clinical and public health policy and practice.



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Research Fellow Rohina Joshi of The George Institute presents findings from the Andhra Pradesh Rural Health Initiative (APRHI)

EXPERT WORKSHOP IN
NEW DELHI,
11-12 APRIL 2006

Recognising the need to collect accurate data on causes of death in India, representatives from the WHO, World Bank, the Indian Ministry of Health, and various universities attended a workshop to discuss the problem of tracking 'Western' diseases such as stroke and heart attack as they evolve in India and other Asia-Pacific nations.

Hosted by the APRHI Collaborators (The George Institute, The University of Queensland, the Byrraju Foundation, the Centre for Chronic Disease Control and the CARE Foundation) and supported by the Wellcome Trust, the workshop explored the global importance of mortality surveillance systems. Delegates discussed the merits of projects completed in Bangladesh, China, India and Tanzania, and defined an action plan to ensure maximum cost-effectiveness of these systems in resource-poor areas.

Professor Bruce Neal of The George Institute said, "This meeting was a great opportunity to inform our research goals and move forward a key issue in the monitoring of global health. The work we are doing is simultaneously enabling our Foundation partner to deliver the health services most urgently required in the villages and allowing us to provide to senior policy makers in the Indian Government robust new evidence about the pace of rural health transition."